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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,105	10/09/2001	Jeffrey H. Baxter	6815.US.01	5606

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EXAMINER

EVANS, CHARESSE L

ART UNIT PAPER NUMBER

1615

DATE MAILED: 09/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/973,105

Applicant(s)

BAXTER, JEFFREY H.

Examiner

Charesse L. Evans

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) 7-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Action Summary

Acknowledgement is made of the receipt of applicant's amendment and response to election requirement, filed July 21, 2003.

Acknowledgement is made of the cancellation of claims 7-43.

Claims 1-6 are active in this action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Sasaki Kazuyuki et al (JP 10101576 A2). The claims are directed to a method for providing glutamine supplementation to a human comprising administration of N-acetyl L-glutamine, wherein the human suffers from various gastrointestinal ailments.

Sasaki teaches the administration of acetyl glutamine for the treatment of digestive disorders such as ulcerative or inflammatory digestive tract diseases,

digestive tract damage caused by digestive tract removal, radiation or parenteral nutrition (Abstract).

Sasaki teaches every aspect of claims 1 and 6, thus anticipating claims 1 and 6.

Claims 1-3 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Kihlberg et al (US 5,462,924).

Kihlberg teaches a product containing N-acetyl L-glutamine, for the treatment or prevention of malfunction or disease of the intestinal mucosa as well as the use of these components for the manufacture of a medicament or a kit for the treatment or prevention of malfunction or disease of the intestinal mucosa (column 3, lines 59-63). Kihlberg further teaches that the glutamine can be administered in amounts ranging from 0.01 to 1g/kg per day (column 4, lines 33-36, and claims 10-11).

Kihlberg teaches every aspect of claims 1-3 and 6, thus anticipating claims 1-3 and 6.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1- 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kihlberg et al (US 5,462,924) in view of Crawford (US 4,994,457).

Kihlberg teaches a product containing glutamine, for the treatment or prevention of malfunction or disease of the intestinal mucosa as well as the use of these components for the manufacture of a medicament or a kit for the treatment or prevention of malfunction or disease of the intestinal mucosa (column 3, lines 59-63). Kihlberg further teaches that the glutamine can be administered as N-acetyl L-glutamine in amounts ranging from 0.01 to 1g/kg per day (column 4, lines 33-36, and claims 10-11).

Kihlberg does not expressly teach the salts of N-acetyl L-glutamine, however, Crawford is being supplied to demonstrate (exemplified in literature authored by Tanaka et al, Japan. J. Pharmacol., v.32, pp. 307-313 (1982)) that it is well-known in the art to utilize the aluminum salts of N-acetyl-L-glutamine to prevent the exacerbation of gastric ulcers in rats (column 2, lines 1-6).

While the reference does not expressly teach applicant's exact concentrations of N-acetyl L-glutamine, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are

disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

One of ordinary skill in the art would have been motivated to manipulate the amounts of the disclosed reference, with the expectation of optimizing a formulation that is most effective in the treatment of gastrointestinal disorders.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charesse L. Evans whose telephone number is 703-308-6400. The examiner can normally be reached on Monday - Thursday 7:00a - 4:30p; Alternating Fridays 7:00a - 3:30p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Charesse L. Evans
Examiner
Art Unit: 1615

September 11, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNICAL CENTER 1600